PROGRESS ASSESSMENT CHECKLIST FOR NINDS CLINICAL STUDIES

This checklist outlines a review for on on-going studies, focusing on study data collection, study documentation, and patient safety.

Note: NINDS has established these guidelines as a resource for items that KAI may review during a site visit. Definitions of underlined terms are available in the NINDS Glossary.

		YES	NO	NA
A.	Overview - Study Administration and Procedures			
1.	Is there a **Master Study File** that contains study documents necessary for the conduct of the clinical study and, if applicable, includes **essential study documents** from each study site?	☐	☐	☐
2.	*Are the following documents on file in the Master Study File:*			
	a) **Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approvals**	☐	☐	☐
	b) Approved version of **informed consent**, **protocols**, and **protocol amendments** for each study site	☐	☐	☐
	c) Foreign clearance for international clinical sites.	☐	☐	☐
	d) Study Site **annual reviews** and site status reports from all clinical sites	☐	☐	☐
	e) IRB/IEC compositions or **Federal Wide Assurance #s (FWA)**	☐	☐	☐
	f) **New Drug Application (NDA)** / **Investigational New Drug Application (IND) / Investigational Device Exemption (IDE)** information if applicable.	☐	☐	☐
	g) CVs, licenses, and certifications for PI, co-investigator(s), **Clinical Research Coordinators (CRCs)**, and Pharmacists.	☐	☐	☐
	h) Screening logs	☐	☐	☐
	i) Monitoring Reports	☐	☐	☐
	j) **Financial disclosure/conflict of interest** documentation	☐	☐	☐
3.	**Site Signature Log/Delegation of Authority** signed by all study staff and signed off by Principal Investigator (PI)?	☐	☐	☐
4.	Have the **Safety Monitoring Body (SMB)** and NINDS provided approval for study initiation?	☐	☐	☐
5.	Is there a letter of agreement from drug or device company donating study supplies, i.e. active drug, placebo, device (if applicable)?	☐	☐	☐
6.	Is there documentation of SMB or **Medical Safety Monitor (MSM)** submissions to the local IRB/IEC?	☐	☐	☐
7.	Are there copies of study communications with sites and other centers (i.e. **Statistical Analysis Center (SAC)** and **Data Coordinating Center (DCC)** ?	☐	☐	☐
8.	Is there documentation of **adverse events (AEs)**/**serious adverse events (SAEs)** with copies of reports and follow-up correspondences?	☐	☐	☐

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		YES	NO	NA
9.	Is there documentation of attendance and training for investigators and staff at **Investigator Meetings or Site Initiation Visits**?	☐	☐	☐
10.	Has the **Manual of Procedures (MOP)** been distributed to all clinical sites and updated as needed?	☐	☐	☐
B.	**Safety Plan**			
11.	Is a **Safety Monitoring Plan** in place that outlines independent oversight in the form of a SMB or MSM?	☐	☐	☐
12.	Does the Safety Monitoring Plan provide a clear communication structure for SMB or MSM involvement in study events?	☐	☐	☐
13.	Are there definitions for serious adverse events and adverse events?	☐	☐	☐
14.	Are there procedures in place for documenting and reporting AEs, SAEs, and **unexpected AEs**, according to NIH Guidelines (http://grants.nih.gov/grants/guide/notice-files/not99-107.html)?	☐	☐	☐
15.	Are human subjects protection provisions in place in accordance with NIH and **HIPAA** (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)?	☐	☐	☐
16.	Are there clearly defined **stopping rules** in place?	☐	☐	☐
D.	**Study Communications**			
17.	Have detailed communication processes been developed to describe communication flow, handling of inquiries, and emergency situations?	☐	☐	☐
18.	Have the necessary investigator meetings and teleconferences between committees been scheduled?	☐	☐	☐
C.	**Training**			
19.	Has all study staff had initial training and certification in clinical research or **good clinical practices (GCP)**, i.e. human subject's protection, HIPAA, etc.?	☐	☐	☐
20.	Has all study staff had initial training on the study protocol and procedures either at an investigator meeting or site initiation visit?	☐	☐	☐
21.	Has human subjects' protection training been documented for all study staff?	☐	☐	☐
22.	Are procedures in place to modify training, if necessary, so clinical center personnel accurately collect data according to the updated procedures specified in the revised protocol?	☐	☐	☐

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		YES	NO	NA
23.	Is there data collection and data entry training provided on the necessary study data management system?	☐	☐	☐
D.	**Recruitment**			
24.	Is there a recruitment plan that maps out all the steps, methods, and research team member responsibilities for the recruitment efforts?	☐	☐	☐
E.	**Screening and Informed Consent**			
25.	Is there a process in place during the **pre-screening and screening process** so that data on eligible and ineligible individuals are captured in an appropriate format?	☐	☐	☐
26.	Is there a written procedure to ensure that the current copy of the IRB/IEC approved informed consent form is signed before any tests or procedures are administered?	☐	☐	☐
27.	Is the informed consent clearly written and easy to understand in various languages as necessary?	☐	☐	☐
28.	Are procedures in place to ensure that the informed consent process is described by study staff to the patient?	☐	☐	☐
F.	**Enrollment and Randomization**			
29.	Are there written procedures for the enrollment process, including documentation of enrollment in an **enrollment log**?	☐	☐	☐
30.	Do procedures document inclusion and exclusion criteria so that appropriate participants can be enrolled?	☐	☐	☐
31.	*Does the **Randomization Plan** include procedures for the following:*			
	a) Ensure participants randomized correctly	☐	☐	☐
	b) Maintain confidentiality of the randomization code	☐	☐	☐
	c) Verify correct **randomization code** number is assigned	☐	☐	☐
	d) Assigned code stays with participant through entire study	☐	☐	☐
	e) Are **masking/blinding** and **unmasking/unblinding procedures** in place to limit unmasking/unblinding?	☐	☐	☐
G.	**Study Retention/Patient Follow-Up**			
32.	Are there written procedures that outline methods for participant retention in the study?	☐	☐	☐
33.	Do the procedures include follow-up of participants who have missed visits or are lost to follow-up?	☐	☐	☐
H.	**Concomitant Medications**			
34.	Have forms been created to collect all necessary information?	☐	☐	☐

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		YES	NO	NA
35.	Has the use of concomitant medications been incorporated into the **inclusion**/**exclusion** criteria?	☐	☐	☐
36.	Is there a process to compare concomitant medications and AEs?	☐	☐	☐
I.	**Data Collection**			
37.	Is there a schedule of participant contacts (i.e. study visits)?	☐	☐	☐
38.	Are there written procedures that guide data collection at each participant contact (i.e. source document and case report form completion)?	☐	☐	☐
39.	Are forms organized by visit?	☐	☐	☐
40.	Is there a complete description and definition of how each data item is to be collected on each study form for each participant contact?	☐	☐	☐
41.	Do the forms and data collected at each participant contact correspond to and reflect the data analysis plan?	☐	☐	☐
42.	Are there written plans for obtaining, handling, storing, and sending patient samples/materials?	☐	☐	☐
43.	Are there written procedures for obtaining and transmitting laboratory data as well as the laboratory results?	☐	☐	☐
44.	Are there AE forms and do they include the necessary data to generate safety reports?	☐	☐	☐
J.	**Data Management**			
45.	Is there a **Data Management Plan** or do written procedures document data handling from collection through analysis?	☐	☐	☐
46.	Are all study documents, including protocol, manual of procedures (MOP), data collection forms, statistical analysis plan, etc. reflected in the data management procedures?	☐	☐	☐
47.	Is there a detailed description of how forms are sent or transmitted to the data coordinating center (if applicable)?	☐	☐	☐
48.	Are there procedures in place that identify and track the status of each participant throughout the study?	☐	☐	☐
49.	Are there tracking procedures that document and confirm data collected, forms completed, and forms received at the data collection/coordinating center?	☐	☐	☐
50.	Are there written procedures that describe how data are transferred from paper into a computer system, edited, and moved to an analysis data base, as relevant?	☐	☐	☐
K.	**Quality Standards**			

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		YES	NO	NA
51.	Have quality standards been established for enrollment and accrual deviations, protocol deviations, drop-outs, and data entry and analysis?	☐	☐	☐
52.	Are procedures in place for correcting inaccurate data and documenting the changes systematically?	☐	☐	☐
53.	Are procedures in place for amending the protocol and the MOP and documenting the changes systematically so that changes can be tracked?	☐	☐	☐
54.	Has a drug/device plan been established which includes procedures for shipping, distribution, maintaining inventory, return and destruction of drug or device?	☐	☐	☐
L.	**Compliance and Monitoring**			
55.	Is there a comprehensive monitoring plan which details frequency of site visits, what is reviewed, etc.?	☐	☐	☐
56.	Are screening, recruitment, enrollment, and retention reports reviewed regularly and action plans documented?	☐	☐	☐
57.	Are protocol compliance reports reviewed regularly and protocol deviations documented systematically?	☐	☐	☐
58.	Are reports that describe missing or erroneous data reviewed regularly to detect and correct problems?	☐	☐	☐
59.	Are **site monitoring reports** designed to provide feed back regarding problems and issues discovered during site visits and to report on the quality of data reviewed?	☐	☐	☐
60.	Are procedures in place to ensure the necessary follow-up of outstanding issues as a result of site visits and a means of documenting plans moving forward?	☐	☐	☐
M.	**Facilities**			
61.	Are study documents (i.e. **study file**, subject binders, etc.) stored in a secure cabinet with limited access only to authorized study personnel?	☐	☐	☐
62.	Are study drugs/devices stored in a secure locked location and only handled by the Pharmacist or authorized study personnel as stated in the Drug/Device Plan?	☐	☐	☐
63.	Are reference ranges, certification, and temperature logs for applicable equipment (i.e. refrigerators, biological cabinets, etc.) needed for storage or handling of the study drug/device current and being maintained?	☐	☐	☐
64.	Is the informed consent being administered in a private area that offers protection of the patient's confidentiality?	☐	☐	☐

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		YES	NO	NA
65.	Are clinical areas (i.e. exam rooms, x-ray, blood draws, etc.) specially reserved for the conduct of the study to uphold patient confidentiality?	☐	☐	☐
N.	**Study Completion**			
66.	Have all necessary queries and CRFs been completed?	☐	☐	☐
67.	Has the final study close-out visit been completed?	☐	☐	☐
68.	Has the study drug/device been either returned or destroyed according to the Drug/Device Plan?	☐	☐	☐
69.	Is a publication/dissemination policy in place for study data?	☐	☐	☐